REMARKS

I. INTRODUCTION

Claims 1, 3, 13, 14, 19 and 37 have been amended. Claims 38 and 39 have been added. No new matter has been added. Thus, claims 1-39 are now pending in the present application. In light of the above amendments and the following remarks, Applicants respectfully submit that all presently pending claims are in condition for allowance.

II. THE 35 U.S.C. § 103(a) REJECTIONS SHOULD BE WITHDRAWN

Claims 1, 8, 12-14, 31, 36, and 37 stand rejected under 35 U.S.C. §103(a) for being obvious over Shaffer et al. (U.S. Patent No. 5,335,650) (hereinafter "Shaffer '650") in view of Shaffer et al. (U.S. Patent No. 6,105,572) (hereinafter "Shaffer '572").

Claim 1 has been amended to recite, "[a] method of applying total liquid ventilation to a patient according to a ventilation cycle including inspiration and expiration profiles, comprising: supplying oxygenated liquid to the lungs of the patient during inspiration; withdrawing liquid from the patient's lungs during expiration; and controlling independently supply of oxygenated liquid to the patient's lungs and withdrawal of liquid from the patient's lungs, the supply and withdrawal independent control comprising producing a ventilation cycle having independently controlled, *different inspiration and expiration profiles using independent inspiration and expiration controllers*."

The Examiner indicates that Shaffer '650 describes the feature of independently controlling the supply and withdrawal of liquid to/from the patient via a ventilator controller (50) having independently controlled inspiration and expiration profiles. (See 5/1/09 Office Action, p. 3). Specifically, the Examiner refers to column 15, lines 35-55 and column 16, lines 50-65 of Shaffer '650.

Shaffer '650 discloses that, during inspiration, liquid is circulated by a pump 10 from an inspiratory liquid reservoir 11 through inspiratory valve 12 to patient 14 via line

15. Valve 12, in combination with pump 10, determines the following parameters associated with the inspiratory liquid delivered to the patient during the inspiration cycle: inspiratory liquid flow rate, inspiratory time, peak inflation pressures, inspiratory tidal volume, inspiratory lung volume and inspiratory breathing frequency. (See Shaffer '650, col. 15, ll. 40-49).

Shaffer '650 also discloses that, during expiration, liquid is circulated by pump from patient 14 through expiratory valve 25 to expiratory liquid reservoir 26 via line 27. Valve 25, in combination with pump 24, determines the following parameters associated with the expiratory liquid removed from the patient during the expiration cycle: expiratory liquid flow rate, expiratory time, peak deflation pressures, expiratory tidal volume, expiratory lung volume and expiratory breathing frequency. (See Id., col. 16, ll. 53-61). Shaffer '650 further discloses that CPU 50 can be designed to generate a signal to correct the excessive lung volume by manipulating pump 10, valve 20, pump 24 and valve 25 via lines 19, 20, 30 and 31, respectively. (See Id., col. 17, ll. 65-68).

Accordingly, Shaffer '650 presents a system for controlling two (2) pumps using typical respiratory parameters such as inspiratory and expiratory liquid flow rates, inspiratory and expiratory times, peak inflation and deflation pressures, inspiratory and expiratory tidal volumes, inspiratory and expiratory lung volumes and inspiratory and expiratory breathing frequency.

Shaffer '650 fails to describe two independent controllers for independently controlling the two (pumps). On the contrary, Shaffer '650 describes that a single controller, for example CPU 50 can be designed to generate a signal to correct the excessive lung volume by manipulating both pumps 10 and 24. (See Id., col. 17, ll. 65-68). As indicated in paragraph [0076] of the published specification, independent control of the inspiratory 7 and expiratory 8 pumps is required to obtain the ventilation profile of Figure 2. As also indicated in paragraph [0109] of the published specification, position control of the pump pistons as well as independent control of the motor drives enables the implementation of complex ventilation profiles which otherwise would not be possible.

Moreover, Shaffer '650 fails to describe the inspiration and expiration profiles. In particular, Shaffer '650 fails to describe independently controlled, different inspiration and expiration profiles. The figures of Shaffer '650 seem to indicate that the inspiration and expiration profiles are the same.

The Examiner correctly acknowledges that Shaffer '650 does not specifically mention whether the liquid ventilation is total or mixed-mode. (See 5/1/09 Office Action, p. 3). To cure this deficiency, the Examiner refers to column 1, lines 1-10 of Shaffer '572 states that Shaffer '572 discloses a similar liquid ventilator with inspiration and expiration pumping systems for performing total liquid ventilation. However, it is respectfully submitted that Shaffer '572 (in particular the passage of column 1, lines 1-10 identified by the Examiner) simply provides a definition of total liquid ventilation.

In the rejection of claims 13 and 37, the Examiner indicates that Shaffer '650 discloses modifying the inspiration and expiration profiles. It is respectfully submitted that Shaffer '650 does not define the pause between the inspiration and expiration profiles and the pause between the expiration and inspiration profiles as defined in claims 13 and 37. Accordingly, newly added claims 38 and 39 define these pauses.

Applicants, therefore, respectfully submit that Shaffer '650 and Shaffer '572, taken alone or in combination, fail to disclose or suggest "*different inspiration and expiration profiles using independent inspiration and expiration controllers*," as recited in claim 1 and that claim 1 is allowable. Because claims 8 and 12-13 depend on and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 14 recites "a ventilation cycle control means comprising first and second independent pump controllers connected to the inspiration and expiration pumps, respectively, to control independently said inspiration and expiration pumps in order to produce a ventilation cycle having independently controlled, different inspiration and

expiration profiles." Thus, claim 14 and its dependent claims 31, 36, and 37 are also allowable for at least the foregoing reasons presented with regard to claim 1.

Claims 2-7, 9-11, 15, 16, 19, 27-30, and 32-35 stand rejected under 35 U.S.C. §103(a) for being obvious over Shaffer '650 in view of Shaffer '572 and further in view of Parker (U.S. Patent No. 5,606,830).

Claim 3 has been amended to recite, in relevant portion, "*withdrawing liquid from the patient's lungs during expiration, wherein withdrawing liquid from the patient's lungs comprises accumulating liquid from the patient's lungs in an expiration piston pump during expiration, and transferring the liquid accumulated in the expiration piston pump directly to the oxygenator unit during inspiration; and controlling independently supply of oxygenated liquid to the patient's lungs and withdrawal of liquid from the patient's lungs, the supply and withdrawal independent control comprising producing a ventilation cycle having independently controlled inspiration and expiration profiles.*"

Applicants respectfully submit that Parker fails to cure the above-mentioned deficiencies of Shaffer '650 and Shaffer '572 with regards to claims 1 and 14. Because claims 2 and 9-11 depend on and, therefore, contain all of the limitations of claim 1, it is respectfully submitted that these claims are allowable. Because claims 15, 16, and 27-30 depend on and, therefore, contain all of the limitations of claim 14, it is respectfully submitted that these claims are allowable.

Furthermore, the use of piston pumps enables accumulating oxygenated liquid from the oxygenator in the inspiration piston pump during expiration and subsequently transferring the accumulated oxygenated liquid to the patient's lungs during inspiration, while accumulating liquid from the patient's lungs in the expiration piston pump during expiration and subsequently transferring the liquid accumulated from the patient's lungs to the oxygenator during inspiration. An unexpected result is that the expiration piston pump can be operated, during inspiration, to transfer the liquid accumulated from the patient's lungs during inspiration directly to the oxygenator. In this manner, the time of

residence of the liquid from the patient's lungs in the oxygenator is optimized. Parker cannot reach this unexpected result since the liquid from the patient's lungs is pumped into a reservoir, whereby this liquid is not immediately oxygenated and, therefore, the time of residence of the liquid in the oxygenator is not optimized. (See Parker, col. 5, ll. 32-34, Fig. 1). Accordingly, Parker fails to disclose or suggest "*withdrawing liquid from the patient's lungs during expiration, wherein withdrawing liquid from the patient's lungs comprises accumulating liquid from the patient's lungs in an expiration piston pump during expiration, and transferring the liquid accumulated in the expiration piston pump directly to the oxygenator unit during inspiration*," as recited in claim 3. Moreover, Shaffer '650 fails to cure this deficiency because Shaffer '650 discloses a third pump to supply the liquid from the patient's lungs accumulated in the reservoir to the oxygenator. (See Shaffer '650, col. 15, ll. 40-49, Fig. 9).

Therefore, Applicants respectfully submit that Shaffer '650, Shaffer '572, and Parker, taken alone or in any combination, fail to disclose or suggest "*withdrawing liquid from the patient's lungs during expiration, wherein withdrawing liquid from the patient's lungs comprises accumulating liquid from the patient's lungs in an expiration piston pump during expiration, and transferring the liquid accumulated in the expiration piston pump directly to the oxygenator unit during inspiration; and controlling independently supply of oxygenated liquid to the patient's lungs and withdrawal of liquid from the patient's lungs, the supply and withdrawal independent control comprising producing a ventilation cycle having independently controlled inspiration and expiration profiles*," as recited in claim 3. It is respectfully submitted that claim 3 and its dependent claims 4-7 are allowable.

Claim 19 recites, "*an expiration pump for withdrawing liquid from the patient's lungs, wherein the expiration pump comprises an expiration piston pump for accumulating liquid from the patient's lungs during expiration, and for subsequently transferring the liquid accumulated from the patient's lungs directly to the oxygenator during inspiration; and a ventilation cycle control means comprising first and second pump controllers connected to the inspiration and expiration pumps, respectively, to*

control independently said inspiration and expiration pumps in order to produce a ventilation cycle having independently controlled inspiration and expiration profiles." Thus, Applicants respectfully submit that claim 19 is also allowable for at least the previously presented reasons with regard to claim 3. Because claims 32-35 depend on and, therefore contain all of the limitations of claim 19, it is respectfully submitted that these claims are allowable.

Furthermore, regarding the rejection of claims 9-11 and 27-30, the Examiner indicates that the modified Shaffer '650 has all the structural limitation/means needed, including a buffer reservoir (26) and means for measuring the patient's lung volumes (32, 33) in order to correct lung volumes as needed.

However, the element (26) of Shaffer '650 is not a buffer reservoir as defined in claims 9-11 and 27-30, for accumulating oxygenated liquid from the oxygenator. In Shaffer '650, the element (26) is a reservoir for accumulating expiration liquid from the patient's lungs before supplying this expiration liquid to the oxygenator. (See Shaffer '650, col. 16, ll. 53-55). The reservoir (26) of Shaffer '650 is not instrumented and the sensors (32, 33) identified by the Examiner are mounted on the elements of connection between the inspiration and expiration reservoirs. (See Id., Fig. 9). There is no indication of the type of sensors, for example sensors of the level of liquid in a reservoir. Also, there is no description that the measurement from the sensors can be used to determine loss of liquid, error in volumes of liquid supplied to or withdrawn from the patient's lungs, etc.

Claims 17, 18, and 20-23 stand rejected under 35 U.S.C. §103(a) for being obvious over Shaffer '650, Shaffer '572, and Parker further in view of Raibel (U.S. Patent No. 5,770,149). Claims 24-26 stand rejected under 35 U.S.C. §103(a) for being obvious over Shaffer '650, Shaffer '572, and Parker further in view of Kumar (U.S. Patent No. 6,983,749).

Regarding claim 17, the Examiner indicates that Shaffer '650 modified by Parker lacks the further specific limitations of the oxygenator, but that Raibel (in Figures 1-3)

teaches an oxygenator comprising: a lower perforated membrane (Figure 3, 74) to supply oxygen to the liquid, an inner cylindrical section having an upper (28) end to which the liquid withdrawn from the patient's lungs is supplied, an outer annular section separated from the inner cylindrical section by a cylindrical partition and communicating with the inner cylindrical section through an annular passage between a lower end of the cylindrical partition and the perforated membrane (see Figure 3); and an outlet (108) for supplying oxygenated liquid from the annular section, said outlet being positioned at a level that determines the level of liquid in the oxygenator.

The oxygenator of Raibel uses semi-permeable membranes or micro-tubes to produce gaseous exchange. Therefore, the oxygenator of Raibel does not use a perforated membrane capable of generating bubbles. The oxygenating portion of Raibel does not define compartments delimited by a cylindrical partition to separate the non-oxygenated liquid supplied to the oxygenator from the oxygenated liquid withdrawn from the oxygenator. The outlet of the oxygenator of Raibel is located at its base. Accordingly, contrary to the wording of claim 17, the level of liquid in the oxygenator is not determined by the level of the outlet. Thus, the oxygenator of Raibel is very different from the oxygenator of claim 17 of the present patent application

Regarding claim 21, the Examiner indicates that Raibel teaches that the oxygenator comprises a lower tubular wall (26); and the heating unit comprises a heating element (12) wound around the lower tubular wall of the oxygenator. However, Raibel describes a heat exchanger positioned at the upper portion of the oxygenator. The heat exchanger of Raibel uses hot water flowing through a tube. In claim 21 of the present patent application, the metallic base of the oxygenator is heated by the heating element to maintain the liquid at the desired temperature.

Regarding claims 22-24, the Examiner indicates that Kumar teaches condensers in a liquid ventilating system for recovering liquid. Reference is made to column 21, lines 53-55. However, the condenser of Kumar is used to recuperate PFC vapors expired by the patient, therefore not generated by an oxygenator of the "bubbler" type. In contrast, in the

present invention the condenser is used to recuperate the PFC vapors created by the oxygenator. Shaffer '650 does not overcome this deficiency since it does not describe the condenser and does not indicate its position. Furthermore, the icing/de-icing cycles are not mentioned in the cited references.

In addition to the above mentioned deficiencies, Applicants respectfully submit that none of Raibel, Kumar, nor Parker cure the previously presented deficiencies of Shaffer '650 and Shaffer '572 with regard to claim 14. Therefore, because claims 17, 18, 20-23, and 24-26 depend on and, therefore, contain all of the limitations of claim 14, it is respectfully submitted that these claims are allowable.

CONCLUSION

In light of the foregoing, Applicants respectfully submit that all of the presently pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, and an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated: September 30, 2009

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